



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

JUL 28 2005

Food and Drug Administration  
College Park, MD 20740

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James W. Barnett, Jr., Ph.D., DAPT  
AAC Consulting Group  
7361 Calhoun Place  
Suite 500  
Rockville, MD 20855-2765

2005Q-0297

RE: Qualified Health Claim Petition – Green Tea and Cardiovascular Disease

Dear Dr. Barnett:

On June 13, 2005, the Food and Drug Administration (FDA) acknowledged receipt of the petition you submitted, on behalf of Ito En, Ltd and Ito En (North America), Inc., pursuant to Sections 403(r)(4) and 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § § 343(r)(4) and 343(r)(5)(D)) and in accordance with the July 10, 2003 Task Force Final Report on the Consumer Health Information for Better Nutrition Initiative. The petition requests a qualified health claim for the relationship between the consumption of green tea and a reduction in a number of risk factors associated with cardiovascular disease.

In accordance with the FDA's guidance, "Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements,"

(<http://www.cfsan.fda.gov/~dms/nuttfoc.html>), FDA is to determine, within 45 days of receipt of a qualified health claim petition, whether the petition is complete and can be filed for further review. The 45-day period for the filing review of your petition is July 28, 2005. Consequently, today we are filing the qualified health claim for green tea and its relationship to cardiovascular disease. The petition is posted on Dockets web page

(<http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm?AGENCY=FDA>) and we are requesting comment on it for 60 days. Interested persons may submit comments until September 26, 2005. Within 225 days of the filing date, we will notify you of our final decision regarding the requested qualified health claim. We have calculated that date to be March 10, 2006.

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Please feel free to contact Vincent de Jesus at 301-436-1450, if you have any questions concerning this petition.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Barbara O. Schneeman", with a long horizontal flourish extending to the right.

Barbara O. Schneeman, Ph.D.

Director

Office of Nutritional Products, Labeling,  
and Dietary Supplements

Center for Food Safety  
and Applied Nutrition